Definition, assessment and rate of psychotherapy side effects

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Psychotherapy is often seen as a first line treatment, because patients and therapists consider this mode of treatment harmless in comparison, for instance, to drug treatment. This assumption is supported by the fact that there are only limited scientific reports on psychotherapy side effects (1,2). There is, however, some evidence which suggests that psychotherapy can have frequent or serious negative consequences, like all effective treatments (3-5).

There are several reasons why awareness of psychotherapy side effects is limited and research on this issue is insufficient. First, the psychotherapist is the "producer" of treatment and therefore responsible, if not liable, for all negative effects, which results in a perceptional bias towards positive rather than negative effects (6). Second, psychotherapy does not only focus on symptoms but also on social behavior, so that the spectrum of possible negative effects is much broader than in pharmacotherapy (7). Third, there is even no consensus on what to call negative: for instance, when evaluating a manuscript on psychotherapy side effects, a reviewer wrote: "a divorce can be both positive and negative, and crying in therapy can reflect a painful experience but can also be a positive and therapeutic event". Fourth, there is a lack of differentiation between side effects and therapy failure or deterioration of illness (8). Fifth, there are no generally accepted instruments for the assessment of psychotherapy side effects and no rules on how to plan scientific studies or monitor side effects in randomized controlled clinical trials (2).

DEFINITION AND ASSESSMENT OF SIDE EFFECTS

There are indeed some instruments for the assessment of negative psychotherapy effects, although they are not widely used. They include the Vanderbilt Negative Indicator Scale (9), the Inventory of Negative Effects (10), the Unwanted Events and Adverse Treatment Reaction Checklist for Psychotherapy (11,12) and the Experience of Therapy Questionnaire (13). Learning from the assessment of side effects in pharmacotherapy, a distinction must be made between side effects, unwanted events, adverse treatment reactions, treatment failure, malpractice effects, side effect profile, and contraindications.

The assessment of side effects must start with the recording of "unwanted events". These are events which occur parallel to or in the context of treatment and which are burdensome to the patient and/or his environment, independent of whether they are unavoidable or even necessary to reach a treatment goal. Scares in surgery or crying in psychotherapy may be unavoidable or even necessary, but if there is a new treatment without this burden to the patient, the old procedure may no longer be ethically appropriate. The UE-ATR checklist (11) provides a list of areas where to look for unwanted events (Table 1).

"Adverse treatment reactions" are all unwanted events which are caused by the treatment. This requires the ascertainment of a causal relation between the unwanted events and the ongoing treatment. In many cases it will not be possible to make a final decision about the cause of an unwanted event. Therefore, a probability rating should be made: e.g., unrelated, probably unrelated, possibly related, probably related, definitely related to the treatment.

Side effects are adverse reactions which are caused by a correct treatment, while malpractice effects are the consequence of an inappropriate treatment. Therefore, a decision must be made on the quality of treatment. Good treatment causes side effects, bad treatment malpractice effects, a distinction which is a prerequisite for the decriminalization of side effects.

Side effects which occur routinely when applying a special type of treatment constitute the "side effect profile" of that treatment. These regularly occurring side effects must be taken into account in planning the therapy, and patients should be informed about the side effect profile before starting treatment. "Contraindications" are serious side effects which must be expected in special types of patients and which render not applicable that type of treatment in those patients.

Finally, the clinical impact of side effects must be assessed. Based on intensity, duration and patient's impairment, a rating of severity is needed. For instance: mild, without consequences; moderate, distressing; severe, in need of countermeasures; very severe, lasting negative consequences; extremely severe, hospitalization required; or life threatening. A suicide would be "extremely severe"; a lay off at work "very severe"; an increase in anxiety "severe"; discussions with one's spouse "moderate"; crying in therapy "mild".

EMPIRICAL DATA ON PSYCHOTHERAPY SIDE EFFECTS

At present, it is not possible to report precise data on the rate and type of side effects of different forms of

Table 1 Areas where to look for unwanted events in psychotherapy (see 11,12)

Emergence of new symptoms
Deterioration of existing symptoms
Lack of improvement or deterioration of illness
Prolongation of treatment
Patient's non-compliance
Strains in the patient-therapist relationship
Very good patient-therapist relationship, therapy dependency
Strains or changes in family relations
Strains or changes in work relations
Any change in the life circumstances of the patient
Stigmatization

psychotherapy. Only very few papers were found when searching in PsycINFO and PubMed, from 1954 until now, for journal articles which have in their title the key word "psychotherapy" in combination with "side effects" (PsycInfo: 12, PubMed: 9), "negative effects" (PsycInfo: 9, PubMed: 4), or "adverse events" (PsycInfo: 2, PubMed: 3). A thorough screening of randomized controlled trials of psychological interventions for mental and behavioral disorders (2) found 132 eligible trials. Only 21% indicated that some type of monitoring of harms had been done, and only 3% provided a description of adverse events as well as the methods used for collection.

An example is the study by Scheeringa et al (14) on trauma-focused cognitive behavior therapy (CBT) for post-traumatic stress disorder (PTSD) in 3 to 6 year old children. They used the Adverse Events Checklist, an 8-item yes/no checklist covering suicidality, homicidality, serious disability, hallucinations, worsening of any previous symptom, appearance of any new symptom, and exposure to new domestic violence, plus an "other" category. Four possible adverse events were reported in 40 patients in the intervention group, while no information was provided for the waiting list control group. Negative events were the worsening of a pre-existing fear of the dark, and the development of enuresis or encopresis. No clear relation to treatment could be established by interviewing children's mothers.

Another example is the study by Piacentini et al (15) on behavior therapy for children with Tourette's syndrome. They compared 61 patients receiving the intervention to 65 children in a supportive therapy group. Adverse events were monitored at each therapy session. Therapists asked about recent health complaints, behavioral changes, visits for medical/mental health care, need for concomitant medications, change in ongoing medications, and hospitalizations. They also offered the opportunity for spontaneous report of any other problem. Affirmative responses prompted further inquiry concerning the onset, severity and outcome of the adverse event and measures taken to address it. Two hundred adverse events were reported during 10 weeks. Of these, 193 were rated as mild or moderate and 7 as severe (broken bones, n=3; concussion, n=1; neck pain, n=1; neck injury, n=1; nausea and vomiting, n=1). None of the severe events was considered treatment related.

In a randomized controlled trial of treatment for PTSD related to childhood abuse (16), skills training in affect and interpersonal regulation (STAIR) plus exposure (N=33) was compared with STAIR plus supportive treatment (N=38) and supportive plus exposure treatment (N=33). Under the heading "adverse effects", it was reported that the percent of participants who dropped out or experienced a worsening of symptoms was significantly higher in the support/exposure group.

Rosen et al (17) conducted a randomized clinical trial to determine the effect of a money management-based therapy on substance abuse or dependence. Unexpectedly, patients assigned to the treatment were more likely to be assigned a representative payee or a conservator than control participants during the follow-up period (ten of 47 vs. two of 43). This is an example of the large spectrum of possible unwanted events.

The few controlled studies document the difficulty of assessing psychotherapy side effects. In particular, it is difficult to discriminate between treatment related side effects and other negative events. The data regularly show lower "side effect rates" in the intervention group as compared to the control groups. To our knowledge, there is no study which explicitly discriminates between unwanted events, adverse treatment reactions, malpractice effects, treatment failure and side effects. Furthermore, it has to be considered that there are many types of psychotherapy and that results from one approach cannot be generalized to the field at large.

There are few specific side effects which have gained special attention. In a controlled study by Sijbrandij et al (18), subjects who had underwent a psychological trauma received emotional debriefing or educational debriefing or no debriefing. There was no difference in the general outcome between treatments. However, in subjects with high baseline hyperarousal, there were significantly more PTSD symptoms at 6 weeks than in control participants after emotional debriefing. This result has been confirmed by other studies (19). Another example of a specific side effect is the generation of false memories: it is well known that psychotherapy can lead to the development of subjectively convincing "memories" of something which never happened, for instance sexual abuse (20,21). The frequency of this side effect is unknown, but it must be sufficient to justify the existence of a False Memory Syndrome Foundation in the U.S..

Another way to estimate side effects of psychotherapy are patient and therapist surveys. In a survey with 1504 patients, using a specifically developed questionnaire with 61 items, Leitner et al (22) found significant differences between treatment modes. Patients reported "burdens caused by therapy" in 19.7% of cases when treated with CBT, 20.4% with systemic psychotherapy, 64.8% with

humanistic psychotherapy, and 94.1% with psychodynamic psychotherapy. Examples of burdens are that patients felt overwhelmed in therapy, were afraid of the therapist, or were afraid of stigmatization.

An example of a therapist survey is provided by Löhr and Schmidtke (23). They contacted 418 CBT therapists by mail, 232 of whom filled in a questionnaire. Therapists estimated that on average 8% of patients left their spouse after treatment, which in 94% of cases was regarded as not to be due to the intervention.

In summary, there is an emerging consensus that unwanted events should be expected in about 5 to 20% of psychotherapy patients (3-5,12). They include treatment failure and deterioration of symptoms, emergence of new symptoms, suicidality, occupational problems or stigmatization, changes in the social network or strains in relationships, therapy dependence, or undermining of self-efficacy. Rates may vary depending on patient characteristics (suggestible persons), diagnosis (personality disorders), patient expectations (social benefits), severity of illness (severe depression), therapist characteristics (demanding) or special therapeutic techniques (exposure treatment, self-revelation) (13,21).

CONCLUSIONS

Despite the lack of sound empirical data, one can conclude that psychotherapy is not free of side effects. Negative consequences can concern not only symptoms, like an increase in anxiety, or course of illness, like enduring false memories, but also negative changes in family, occupation or general adjustment in life. Consequences like job loss or divorce can be lasting, costly and detrimental for the patient and his/her environment.

As therapists and scientists alike are to some degree salesmen of "their" treatment, they are as trustworthy as pharmaceutical companies. They have good intentions and conflicts of interest as well. Like in pharmacotherapy, structures are needed to safeguard good clinical practice.

As side effects must be discriminated from malpractice, protocol adherence and quality control in psychotherapy is of utmost importance. Psychotherapists who implement idiosyncratic therapies will have to deal with a reversal of burden of proof when it comes to adverse treatment reactions.

As psychotherapy side effects are multifold and sometimes difficult to detect, good, practical and generally accepted assessment instruments are needed. Therapists should be trained in the recognition, evaluation and documentation of side effects, and learn how to plan treatment taking possible negative consequences into account.

It should be mandatory for all controlled clinical trials in psychotherapy research to thoroughly look for unwanted events and side effects. More reliable data are needed in order to allow an estimate of the true risks of psychotherapy.

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